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Dockets Management Branch
Docket No. 98N-0331
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane (HFA-305), Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

These comments are offered by Entela, Inc. on the June 12, 2000 draft document entitled, "Guidance for Staff, Industry and Third Parties, Implementation of Third Party Programs Under the FDA Modernization Act of 1997 – June 2000.

Founded in 1974, Entela, Inc. is an integrated engineering and testing laboratory that provides engineering and design, testing, system integration, quality assurance and compliance services with industry standards in the automotive, furniture, consumer product, electronics, aerospace, nuclear and medical industries. Entela is an ISO 9000/QS 9000 registrar, an OSHA-approved Nationally Recognized Testing Laboratory (NRTL) and also operates association-sponsored third party certification programs. Entela is an Accredited Person (AP) and is approved for all medical specialty areas currently eligible for review by third parties

In general, Entela's comments fall into three broad categories: (1) eligibility to participate in the expanded program, (2) guidance documents, and (3) conflict of interest issues.

Eligibility to Participate in the Expanded Third Party Review Program

In general, the eligibility criteria for third parties to participate in the program is unduly restrictive. The draft guidance document states:

> *An Accredited Person may review a Class II device that does not have device-specific guidance if:*
>
> *1) The Accredited Person has previously completed three successful 510(k) reviews under the third party program. This should include at least one 510(k) review that was in the same or similar medical specialty area as the device the Accredited Person now intends to review. The prior 510(k) reviews can be for Class II devices that have device-specific guidance or for Class I devices;*

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2) The Accredited Person contacts the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) before initiating a 510(k) review for a Class II device that does not have a device-specific guidance to confirm that the Accredited Person meets the criteria in paragraph 1 above for review and to identify pertinent issues and review criteria related to this type of device; and

3) The Accredited Person prepares a summary documenting the discussions and submits the summary of those discussions to ODE.

Limiting eligibility to review Class II devices for which there is no device-specific guidance to Accredited Persons that have previously reviewed three successful 510(k)s under the third party program appears reasonable. This is because it is prudent to have experienced Accredited Persons reviewing higher-risk devices. In addition, individuals wishing to enter the third party program can always apply to FDA to become an Accredited Person by participating in an FDA training program.

However, the restriction that at least one of the three reviews be in the same or similar medical device specialty area as the device the Accredited Person now intends to review is unduly restrictive. This is because an Accredited Person could be denied the ability to conduct a product review in a medical specialty area for which they have been previously accredited or have previous technical knowledge.

FDA should commit to holding training seminars for Accredited Persons for the devices subject to this program expansion. Without training and seminars, and based on the current eligibility criteria, the number of Accredited Persons that can participate in the program will be severely limited. This will slow the pace of program expansion and the total number of products that will be covered under the program.

Entela is also concerned about the number of devices being made eligible under the expanded program and it's relationship with the "duration" language under Section 523 (c) of FDAMA. While the proposed list is quite extensive and may strictly meet the requirements of 523(c) (2) and trigger the sunsetting of the program, by drafting such strict eligibility criteria, the express intent of the statute will be frustrated because 35% of eligible devices will never be reviewed by third parties.

"De Facto" Guidance Documents

The eligibility criteria reproduced above [items 2) and 3)] have the effect of creating "de facto" guidance documents, but with the responsibility to develop these documents squarely on the shoulders of the Accredited Person. This clearly will be a time-consuming and expensive requirement.

Therefore, since the classes of devices that are the subject of this expansion are currently being reviewed by the FDA, Entela suggests that currently existing internal FDA "review memos" and any other non-redacted pertinent documents that would be helpful in the review process be made available to any Accredited Person that is retained by a device manufacturer to prepare a 510(k) under the expanded program. For example, copies of the latest 510(k) for that device and the

referenced Substantial Equivalent device should be made available. Confidentiality should not be an issue. All Accredited Persons are subject to the same confidentiality requirements as FDA personnel.

Conflicts of Interest

On pages 14 and 15 of the draft guidance document, conflicts of interest are discussed. It is stated that

> *Business relationships that may undermine the independence or objectivity of an accredited person include contracts with a manufacturer and an accredited person that represent a significant share of the accredited income over the period of the contract, such that continuation or termination of the contract may create the appearance of an undue financial influence.*

As stated earlier, Entela is an independent, international conformity assessment organization with a variety of business streams in the testing, certification and quality systems arenas. It's accredited persons are full-time employees. In Entela's case, it is highly unlikely that the business relationships that FDA envisions would apply to Entela. In addition, Entela has formal procedures in place to address conflict of interest issues.

On the other hand, such a situation is far more likely for individual consultants. However, Entela contends that FDA's position is untenable nonetheless since it is inconsistent with draft eligibility criteria, where it is clear that FDA desires experienced reviewers. When the current eligibility criteria and conflict of interest criteria are read together, there is very little incentive for an Accredited Person to develop specialized experience in a niche market for specific manufacturers out of fear of creating the appearance of undue financial influence.

Conclusion

As with the first 510(k) pilot program, Entela believes that the FDA continues to struggle with how to fairly privatize medical device review. From delegating to the private sector the development of "de facto" guidance documents to inconsistent and unduly burdensome conflict of interest and eligibility criteria, FDA has set up a program to fail. We would be happy to meet with FDA to discuss our comments in more detail and appreciate the opportunity to comment.

Sincerely,

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